

Notice of Allowability

Application No.

09/609,552

Applicant(s)

MURRAY, MICHAEL F.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to September 9, 2004.
2. ☒ The allowed claim(s) is/are 1 and 19-23, 25-29.
3. ☒ The drawings filed on 30 June 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SHENGJUN WANG
PRIMARY EXAMINER

DETAILED ACTION

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Meaney on April 11, 2005.

Amend the application as follow:

In the claims, cancel claims 14-18, 30-33, amend claims 1 as follow;

Claim 1. A method of increasing systemic tryptophan comprising the administration of an effective amount of niacin for increasing systemic tryptophan to a patient in need of an increase in systemic tryptophan wherein the patient is infected with a retrovirus and wherein the patient has a diet that includes at least the RDA (recommended daily allowance) of niacin and Tryptophan, wherein the effective amount is approximately 3 gram per day.

Reasons for Allowance

2. Applicants' notice of appeal have been fully considered. The arguments as to the rejections under 35 U.S.C. 112 are found persuasive. Particularly, it should have been with in the skill of artisan for determination of the effective amounts that increase the plasma level of tryptophan. Further, it is noted that there is no limitation as to how much the increase is. Applicants' arguments as regarding to the rejections under 35 U.S.C. 103 are partially persuasive. The arguments are not fully persuasive because the prior art disclosed that it is

Art Unit: 1617

known HIV infected patients have deficiency of Niacin and the lower intake of niacin was associated to the development of AIDS in HIV infected patients. It would have been obvious to one of ordinary skill in the art to administer HIV infected patient additional niacin in addition to the recommended daily allowance. It is noted that the fact that applicant has recognized another advantage (i.e., increasing tryptophan level) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). However, the cited references come short in suggesting the 3 grams per day dosage, which, as shown in the application, substantially increase the plasma level of tryptophan. The amount herein is much large than what have been fairly suggested (over 100 mg), and the results are unexpected. Therefore, the claims as amended herein are allowable because of the unexpected benefit shown in the specification and the fact that the prior art have not fairly suggested the claimed limitation.

3. Claims 30-33 are not found allowable because the claimed scope therein does not commensurate in scope with the unexpected results. Particularly, the claims read on treating patients other than those with retroviral infection shown in the examples. Further, there are potential new matter issues in these claims. The application as originally filed appears not supporting the broad scope in those claims. Also there is no support for the limitation "91 micromol per liter or less" in the application as originally filed.

Art Unit: 1617

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG Shengjun Wang
PRIMARY EXAMINER Primary Examiner
Art Unit 1617